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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,016	07/10/2001	David L. Thompson	P-9153.05	8319

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EXAMINER	
JASMIN, LYNDA C	

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,016	Applicant(s) THOMPSON, DAVID L.	
	Examiner Lynda Jasmin	Art Unit 3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-32* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment received on December 10, 2004 has been acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Linberg et al. (6,497,655 B1).

Linberg discloses a system of manufacturing to control the customized configuration of an implantable medical device (IMD) [(Fig. 4: IMD (10)] including:

a Web-enabled information network [col. 11, line 23: the communication between programmer (20), and expert data center (62) is web-enabled], a storage device capable of receiving information from the information network to receive patient-specific data (Fig. 4: each of the modules (100, 102, 104) receive and store patient-specific data (e.g., Fig.6: step160)], and a processing circuit coupled to the storage device to select components to be integrated in the initial manufacturing of the IMD based on the patient-specific data (col. 20, lines 19-22: PPM makes recommendation for

upgrade/modifications to be integrated into the IMD). Linberg further discloses software components loaded into the storage device and selected by the processing circuit as one or more of the components selected for use in the configuration of the IMD (Fig. 5). The software components are selected from the group consisting of software and/or firmware-implemented digital signal processing processes (via digital circuit), filters (via wireless communications system through which data and information is transmitted between programmer 20 and data center 62), and signal differentiation processes (via analyzer 106). The processing circuit includes parameter selection means for selecting predetermined parameters to be downloaded into the IMD (col. 9, lines 19-44).

4. Claims 1-3 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (5,725,559).

Alt et al. discloses a system to control the configuration of an implantable medical device (IMD) (Fig. 4C: device 10 is a programmable implant) including: a Web-enabled information network (col. 4, line 55: the communication between programmer (40) and manufacturer is via Internet (i.e., web-enable)), a storage device capable of receiving information from the information network (col. 9, line 11 through col. 10, line 9; discloses programmer (40) to be a computer therefore, it must necessarily store the information in order to perform the stated functions) to receive patient-specific data (col. 4, lines 50-52: the upgrade data received from the manufacturer via the internet is "patient-specific" in that it requires a specific device serial number, i.e., a unique ID associated with a specific device implanted in a specific patient), and a processing circuit coupled to the storage device to select components to be integrated in the IMD based on the patient-

specific data (Fig. 4C; col. 9, lines 46-53: the patient specific upgrade data received is used to determine which functions to enable/disable in the implant device (10)).

Alt further discloses software components loaded into the storage device (Fig. 3) and selected by the processing circuit as one or more of the components selected for use in the configuration of the IMD (col. 8, lines 15-34). A manufacturing system coupled to receive Information Indicative of the selected components, wherein the received Information is used during manufacture of the IMD (via col. 4, lines 23-48). Alt further discloses a testing system to receive information indicative of the selected component, wherein the received information (such as signals generated from the patient-specific data) is used in testing a manufactured IMD (col. 8, line 64 - col. 9, line 10). The processing circuit includes means for selecting hardware components to be used during manufacture of the IMD based on the patient-specific data (col. 4, lines 4-22).

5. Claims 12-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. (5,725,559), in view of Colligan et al. (6,298,443).

Alt et al. discloses all the elements of the claimed invention a medical device manufacturing as disclosed in paragraph 9 above, and further discloses customized order including physiological data and modifying a selected software algorithm based on the physiological data [via sensor means (12): col. 6, lines 36-55]. However, Alt fails to explicitly disclose monitoring inventory levels and transferring customized orders to for the IMD from a remote site to the inventory management.

Colligan et al. discloses the concept of maintaining and inventory via an asset tag (col. 11, lines 24 and 25). Colligan et al. further discloses the concept of having a build-to-order custom-programmed CD ROM that is configured for a specified individual computer system (with Service Tag number of the specified computer system) and constraint to be downloaded to and operable on only the specified individual computer system. Colligan et al. also discloses a software transport package manufacturing process (300) to retrieve customer order record by part number and a shipping method.

From this teaching of Colligan et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modify the upgradable implanted medical device of Alt et al. to include the customized order fulfillment taught by Colligan et al. in order to fit customer's specific needs.

Allowable Subject Matter

6. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant argues that Alt neither describes not depicts any customization during initial manufacture of the device but contrary to applicant's arguments, this kind of device is usually customized to patients' specifications. Each implant varies from patient to patient and by customizing the device, the system is capable of providing

additional therapy specific to said patient. Applicant further argues that the Examiner has failed to lodge a prima facie obviousness rejection and that there is no suggestion or motivation to combine the references. It is not necessary that the references actually suggest, expressly or in so many words, the changes or improvements that applicant has made. The test for combining references is what the references as a whole would have suggested to one of ordinary skill in the art. In re Sheckler, 168 USPQ 716 (CCPA 1971); In re McLaughlin 170 USPQ 209 (CCPA 1971); In re Young 159 USPQ 725 (CCPA 1968). Applicant's arguments are deemed unpersuasive, claims 1-32 are finally rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lynda Jasmin 3/11/05
Primary Examiner
Art Unit 3627

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